Application No.: 10/578,452 Amendment dated October 4, 2010 Reply to Office Action of June 4, 2010

Docket No.: 30572/42052

REMARKS

I. **Preliminary Remarks and Amendments**

Claims 1-11 are currently pending. Claims 5-9 are withdrawn. Thus, claims 1-4 and 10-11 are under examination in the present application. Claims 1-4 and 10-11 are rejected. Claims 10 and 11 are subject to objection for asserted improper dependent form.

Claims 1-4 and 10-11 were rejected under 35 U.S.C. § 101, as assertedly lacking utility.

Claims 1-4 and 10-11 were rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Heidland et al. (American Heart Journal 139(3), 2000; hereinafter "Heidland").

Claims 1-4 and 10-11 were rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Cross et al. (U.S. Patent No. 4,217,357, issued August 12, 1980; hereinafter "Cross").

Claims 1-4 and 10-11 were rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the enablement requirement.

Claims 1-4 and 10-11 were rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite.

Claims 1 and 4 are amended herein. Support for the amendment to claim 1 is found in original claims 1, 2 and 3 and throughout the specification, including at page 4, lines 20-29 and line 34, to page 5, line 7. Support for the amendment to claim 4 is found in original claim 4.

Claims 2, 3, 10 and 11 are canceled.

New claims 12-20 are added. Support for new claim 12 is found in original claim 3 and in the specification at least at page 3, lines 26-31; page 4, lines 8-13; page 6, lines 1-4; and page 7, lines 5-9. Support for new claims 13, 14, 16 and 17 is found in original claim 4 and throughout the specification, including at page 4, lines 20-29 and line 34, to page 5, line 7. Support for new claim 15 is found in original claim 3 and in the specification at

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least at page 3, lines 22-26. Support for new claim 18 is found in original claim 2. Support for new claim 19 is found in original claims 1, 2 and 4. Support for new claim 20 is found in original claims 1, 2 and in the specification at least at page 3, line 36, to page 4, line 3; and at page 8, lines 10-27.

Applicants do not intend with these or any other amendments to abandon the subject matter of claims previously presented, and reserve the right to pursue such subject matter in a duly filed continuing patent application. No new matter is added by these amendments.

II. The Rejection Under 35 U.S.C. § 101

The Patent Office rejected claims 1-4 and 10-11 under 35 U.S.C. § 101, as assertedly lacking utility. Specifically, the Examiner asserts that because the claims recite uses without setting forth any steps involved in the process, the claims are improper process claims under 35 U.S.C. § 101. Office Action at pages 6-7.

In response, Applicants have amended the claims to proper method format.

Accordingly, the rejection under 35 U.S.C. § 101 is rendered moot by the amendment.

III. The Rejection Under 35 U.S.C. § 102

A. Heidland

The Patent Office rejected claims 1-4 and 10-11 under 35 U.S.C. § 102(b) as assertedly being anticipated by Heidland. Specifically, the Examiner asserted that Heidland teaches treating cardiovascular disease (i.e. intracoronary stent placement, balloon angioplasty, and myocardial infarction) with dipyridamole, as recited in claim 4. The Examiner argued that because Heidland teaches treating cardiovascular disease with dipyradimole, it is reasonable that dipyradimole is an inhibitor of multi-drug resistance protein 4 (MRP4). Office Action at pages 7-8. Applicants respectfully traverse.

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Nevertheless, in order to expedite prosecution, Applicants have amended claims 1 and 4 to remove dipyridamole from the list of recited compounds and submit that the rejection under 35 U.S.C. § 102(b) is rendered moot.

B. Cross

The Patent Office rejected claims 1-4 and 10-11 under 35 U.S.C. § 102(b) as assertedly being anticipated by Cross. Specifically, the Examiner asserted that Cross teaches treating cardiovascular disease (i.e. ischaemic heart disease and stroke) with dipyridamole, as recited in claim 4. The Examiner argued that because Cross teaches treating cardiovascular disease with dipyridamole, it is reasonable that dipyridamole is an inhibitor of multi-drug resistance protein 4 (MRP4) in platelets. Office Action at page 8. Applicants respectfully traverse.

Nevertheless, in order to expedite prosecution, Applicants have amended claims 1 and 4 to remove dipyridamole from the list of recited compounds and submit that the rejection under 35 U.S.C. § 102(b) is rendered moot.

C. New Claims 12-20

It is further noted by Applicants that none of the cited art discloses or suggests (1) inhibiting MRP-4-mediated storage of ADP or inhibiting transport of ADP *in a platelet* by administering an inhibitor of MRP4 (new claims 12-17); (2) the treatment or prophylaxis of cardiovascular diseases with probenicid or (3-(3-(2-(7-chloro-2-quinolinyl)ethenyl)phenyl)-((3-dimethylamino-3-oxopropyl)thio)methyl)thio)propanoic acid (MK571) (new claim 18); or (3) the treatment or prophylaxis of cardiovascular diseases with an inhibitor of MRP4 wherein the inhibitor's effects can be antagonized by transfusion of platelets (claim 19). Accordingly, new claims 12-20 are not anticipated by Heidland or Cross.

IV. The Rejection Under 35 U.S.C. § 112, First Paragraph

The Patent Office rejected claims 1-4 and 10-11 under 35 U.S.C. § 112, first paragraph, as assertedly lacking enablement. Specifically, the Examiner asserted that the specification enables treating acute coronary syndrome, angina pectoris, and cardiac

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infarction, but does not enable prophylaxis of cardiovascular disease. Office Action at pages 3-5.

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The Examiner cited a paper by Susman et al. (MedPage Today, May 19, 2008; hereinafter "Susman") which examined the use of several drugs in stroke treatment over a 2.5 year period and asserted that Susman discloses that dipyridamole plus aspirin failed to establish non-inferiority with clopidogrel in preventing second strokes, even though the study found little difference between the drugs in effectiveness.

Applicants respectfully disagree with the rejection and with the Examiner's interpretation of what this paper discloses.

First, Susman is a study comparing the effectiveness of two drugs over time in preventing second strokes. Susman says nothing about the use of the drug in the treatment of stroke compared to the prophylaxis of stroke. In addition, at page 2 of Susman, Dr. Ralph Sacco of the University of Miami and a member of the study group stated that "...the results still indicate that either of these drugs can be used to prevent second stroke," and this statement supports the use of the drugs in the prophylaxis of cardiovascular disease. Further, while Susman, published in 2008, was not a paper showing the state of the prior art, Susman demonstrates that even five years after the priority date of the instant application, the authors realized the prophylactic usefulness of these drugs.

The specification (at least at page 1, line 17, to page 2, line 15) teaches prophylaxis of cardiovascular disease by teaching that long-term therapy with oral platelet aggregation inhibitors has an important significance in the treatment of patients with arteriosclerosis both in the context of secondary and primary prevention. Applicants have amended claim 1 to the treatment and/or prophylaxis of a cardiovascular disease *associated with platelet aggregation*, and to include the specific diseases recited in original claim 2. Accordingly, Applicants claims are commensurate in scope with the teaching of the specification.

Accordingly, the rejection of claims 1-4 and 10-11 under 35 U.S.C. § 112, first paragraph, for asserted lack of enablement, has been overcome by the remarks provided above and the amendments to the claims. Thus, the rejection should be withdrawn.

V. The Rejection Under 35 U.S.C. § 112, Second Paragraph

The Patent Office rejected claims 4, 10, and 11 under 35 U.S.C. § 112, second

paragraph, as assertedly being indefinite. Specifically, the Examiner asserts that the phrase

"such as" in claim 4 render the claims indefinite, and the "uses identified by a process" of

claims 10 and 11 without reciting the processes render the claims indefinite. Office Action at

pages 5-6.

In response, Applicants have amended claim 4 to remove the objectionable

language and have canceled claims 10 and 11. Thus, the rejection under 35 U.S.C. § 112,

second paragraph, has been rendered moot.

VI. Conclusion

Applicants submit that all of the outstanding rejections and objections have

been overcome and that claims 1, 4 and 12-20 are now in condition for allowance. The

Examiner is invited to contact the undersigned with any questions, comments or suggestions

relating to the referenced patent application in order to expedite allowance.

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Respectfully submitted,

By__/Lynn L. Janulis/53,066_

Lynn L. Janulis

Lyiii L. Januns

Registration No.: 53,066

MARSHALL, GERSTEIN & BORUN LLP

233 S. Wacker Drive

6300 Willis Tower

Chicago, Illinois 60606-6357

(312) 474-6300

Attorney for Applicants

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